

### **Remarks**

#### **In the Claims**

Claims 26-42, 44-65 and 67-71 are currently pending in the application. As discussed in greater detail below, Applicant has amended claims 26 and 49, and correspondingly canceled claims 28 and 51. Claims 30, 35, 37, 48, 49, 53, and 60 have also been amended. No new matter has been added.

#### **Rejections under 35 U.S.C. §102(b)**

The Office Action rejected claims 26, 35-36, 38, 41-42, 44, 49, 51, 57-59, 61-65, and 69 under 35 USC §102(b) as being anticipated by U.S. Patent No. 5,466,220 issued to Brenneman ("Brenneman"). The Applicant respectfully traverses.

Claim 26 has been amended to recite that the container spiking assembly controller controls the movement of at least a portion of the container spiking assembly to couple the container receptacle with the port assembly. Claim 49 has been amended to recite that the coupling means controls the movement of at least a portion of the positioning means to couple the container receptacle with the port assembly. Support for these amendments can be found at least, for example in paragraphs 0128-0141, and Figs. 9A-9E of the application as filed. Brenneman does not disclose, teach or suggest a spiking assembly controller or coupling means as recited in the claims of the instant application as amended. Given that Brenneman fails to anticipate claims 26 and 49, it follows that Brenneman also cannot anticipate their associated dependent claims.

Therefore, for at least the reasons discussed above, Applicant has shown that Brenneman fails to anticipate claims 26, 35-36, 38, 41-42, 44, 49, 51, 57-59, 61-65, and 69, and therefore respectfully requests withdrawal of their rejection under 35 USC §102(b).

#### **Rejections under 35 U.S.C. §102(e)**

The Office Action rejected claims 26, 35-36, 38, 41-49, 51, 57-59, 61-65, and 69 under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 6,610,040 to Fowles et al. ("Fowles"). Applicant respectfully traverses.

Claim 26 has been amended to recite that the container spiking assembly controller controls the movement of at least a portion of the container spiking assembly to couple the container receptacle with the port assembly. Claim 49 has been amended to recite that the coupling means controls the movement of at least a portion of the positioning means to couple the container receptacle with the port assembly. Support for these amendments can be found at least, for example in paragraphs 0128-0141, and Figs. 9A-9E of the application as filed. Fowles does not disclose, teach or suggest a spiking assembly controller or coupling means as recited in the claims of the instant application as amended.

The Office Action alleges that Fowles discloses “a container spiking assembly controller in communication with the container spiking assembly for controlling coupling of the container receptacle with the port assembly and a liquid controller for controlling the flow of liquid through the port assembly into the container to produce a combined substance and liquid...” The Office Action cites Fowles “cols. 1-13 and claims,” which amounts to the entire specification and claims. Respectfully, in the absence of more specific information, Applicant has been unable to find a disclosure in Fowles that would anticipate each and every element of claim 26 or claim 49 of the instant application as amended. Given that Fowles fails to anticipate claims 26 and 49, it follows that Fowles also cannot anticipate their associated dependent claims.

Therefore, for at least the reasons discussed above, Applicant has shown that Fowles fails to anticipate claims 26, 35-36, 38, 41-49, 51, 57-59, 61-65, and 69, and therefore respectfully requests withdrawal of their rejection under 35 U.S.C. §102(e).

### **Rejections under 35 U.S.C. §103**

The Office action rejected claims 26-34, 37, 39-40, 50, 52-56, 60, 67-68 and 70-71 under 35 U.S.C. §103(a) as being unpatentable over Brenneman in view of U.S. Patent No. 5,466,220 issued to Bloom et al. (“Bloom”). The Office Action also rejected claims 26-34, 37, 39-40, 50, 52-56, 60, 67-68 and 70-71 under 35 U.S.C. §103(a) as being unpatentable over Fowles in view of Bloom. Applicant respectfully traverses both rejections.

The Office Action alleges that Bloom discloses a “controller 207 for controlling coupling of the container and the port assembly (col. 17, ll. 8-26).” Applicant disagrees. First, Bloom in

column 17, lines 8-26 discloses a fluid delivery module 88, which makes contact with cassette 77. This passage does not disclose a controller for controlling coupling of a container or vial with a port assembly. On the other hand, columns 18-20 of Bloom disclose a **holder 207** in the section entitled "Vial Loading Mechanism." The holder 207 is described as part of a vial loading mechanism 200 (col. 18, ll. 21-43). Bloom discloses that "[t]he clinician **forces** the holder 207 to be lowered so that the spike 118 pierces the membrane seal 120 of the vial 85." (col. 19, ll. 38-40, emphasis added).

Furthermore, no combination of the references discloses, teaches or even suggests a controller for controlling coupling of a container (e.g., vial) with a port assembly. The devices disclosed in the references would not readily lend themselves to being adapted for controller-based coupling of a vial with a port assembly. Therefore, a controller-based device would not be a predictable variation of the devices disclosed in the references. In the obviousness analysis, an important consideration is whether "the improvement is more than the predictable use of prior art elements according to their established functions." *See KSR Intl. v. Teleflex Inc.*, 550 U.S. 398, 401 (2007), and MPEP §2141. No combination of the cited references discloses or suggests controller-based coupling as an established function, and none teaches or suggests how such a feature could be implemented given the structure of the devices actually disclosed.

Therefore, for at least the reasons discussed above, Applicant has shown that Brenneman in view of Bloom and Fowles in view of Bloom fail to disclose, teach or suggest all of the elements claimed in independent claims 26 and 49 as amended. Given the patentability of the independent claims, it follows that the associated dependent claims must also be patentable. Applicant therefore respectfully requests withdrawal of the rejection under 35 U.S.C. §103(a) of claims 26-34, 37, 39-40, 50, 52-56, 60, 67-68 and 70-71.

### **Conclusion**

For the foregoing reasons all of the claims of the present invention are patentable over the art of record. It is believed that all of the claim rejections have been addressed and that the application is now in condition for allowance. Reconsideration of the claims and issuance of a notice of allowance are respectfully requested. If any matter arises for which an interview may expedite issuance of a notice of allowance, the Examiner is requested to call the undersigned at the telephone number given below.

Applicant believes that a one-month extension of time is required, and requests that the appropriate extension fee be charged to Deposit Account No. 50-4383. However, if an additional extension of time is required, or if any other fee is required for timely consideration of this application, Applicant requests that the associated fee also be charged to Deposit Account No. 50-4383.

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Respectfully submitted,

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